From: Weniger, Bruce

Sent: Wednesday, 21 March 2001 15:04

To: Baker Barbara (VISI) (E-mail); Bryant Amanda (GA Div Health) (E-mail); Carvell Del (GA) (E-mail); Chaitkin Karen N. (FDA) (E-mail); Clover Richard D. (KY) (E-mail); David (Wyeth WAL) Zabele (E-mail); Davis Robert (GHCPS UWash) (E-mail); Dickson Cindy (Merck) (E-mail); Dumont Don (OR) (E-mail); Easterday Lori (Aventis US) (E-mail); Frederick Varricchio (E-mail); Geoffrey Evans (E-mail); Gilbert, Jayne (Chiron) (E-mail); Halsey Neal (JHU) (E-mail); Hart Patricia L. (Wellstar) (E-mail); Harze Cliff (Merck) (E-mail); Hinman Alan (TaskForce) (E-mail); Irene M. (SBB) Laverence (E-mail); Jack (Wyeth) Barry (E-mail); Jerome Donlon (E-mail); Jones Dennis D. (GA) (E-mail); Kim Joann (AAP) (E-mail); King Arlene (Health Canada) (E-mail); Kirschner Celeste (AMA Coding) (E-mail); Kropas John (WLV Wyeth) (E-mail); Levin James E. (UMN.edu) (E-mail); Long Cyndee (Wyeth/WLV) (E-mail); M Braun (E-mail); Maher Katie (Merck) (E-mail); Maher Lugene (Wyeth) (E-mail); McHugh, Yvonne (Chiron) (E-mail); McKenney Tom (Chiron) (E-mail); Milan (Baxter) Blake (E-mail); Miller John M. (MSMS.org) (E-mail); Morgan Andrew (Medeva) (E-mail); Mundt James (Merck) (E-mail); Norman Baylor (E-mail); Pat Thomas (E-mail 2); Ramirez Jeff (VA) (E-mail); Rennels Margaret (Univ MD) (E-mail); Roberts John (UCC) (E-mail); Ron Filipski (E-mail); Rosofsky Robert (MA) (E-mail); Sarah X. Fan (WAL Wyeth) (E-mail); Saxon-Ellis Mary (SB) (E-mail); Schaffner William (Vanderblt) (E-mail); Seeley Jeff (Merck) (E-mail); Segal Ellie (Chiron) (E-mail); Seppel A. (Wyeth) (E-mail); Sharkey Frank (UCC) (E-mail); Smith Dinny (TX Dept. Hlth) (E-mail); Stevens Kimberlee (WLV) (E-mail); Stuerke Stacy H. (Merck) (E-mail); Susan Ellenberg (E-mail); Terwilliger John (UCC) (E-mail); Thomas (AAP) Saari (E-mail); Tom (Texas D of H) Clark (E-mail); Tom Calabrese (GSK) (E-mail); Toni Stifano (E-mail); Trautmann Gene (TX DofH) (E-mail); Walop Wikke (Health Canada) (E-mail); Watson William (TFCS) (E-mail); Wild Ellen (TFCS) (E-mail); William Purvis (E-mail); Winsnes Randi (Norw Med Contr Auth) (E-mail); Wood Karen (Wellstar) (E-mail); Zimmerman Richard K. (U Pitt) (E-mail); Ali Rashidee (E-mail); Bob (Bob) Chen (NIP) (E-mail); Julie Gamez (E-mail); Pat Thomas (E-mail); Susan Abernathy (E-mail)
Cc: Benjamin Schwartz (E-mail); Beth Hibbs (E-mail); Bill Nichols (E-mail); Egan William (FDA CBER) (E-mail); Frank Destefano (E-mail); Gina Mootrey (E-mail); Harald Heijbel (Sweden) (E-mail); Haygood Dottie (Wellstar) (E-mail); John Livengood (E-mail); Jose Cordero (E-mail); Lance Rodewald (E-mail); Maryann R. Gallagher (FDA) (E-mail); Penina Haber (E-mail); Rob Linkins (E-mail); Scott Loretta (Health Canada) (E-mail); Spika John (Health Canada) (E-mail); Vernon Thomas (Merck) (E-mail); Vitali Pool (E-mail); Walt Orenstein (E-mail)

Subject: Instant draft minutes of today's VISI conference call

Dear VISI working group and cc: recipients,

Below please find instant, draft, brief minutes of today's conference call of the Vaccine Identification Standards Initiative. This will substitute for more formal, detailed minutes which are no longer possible with the departure of Bindi Patel from CDC's VISI team.

Please advise me of any omissions, suggested additions, and corrections (spelling, as well as my interpretation of the discussion content) that are needed.

Bruce

Assistant Chief for Vaccine Development
Vaccine Safety and Development Branch
National Immunization Program
Centers for Disease Control and Prevention

Postal Mail: 1600 Clifton Road (E-61)
Atlanta, GA 30333 USA
Couriers: 12 Corporate Boulevard
Atlanta, GA 30329 USA

Tel: [+1] 404-639-8779
Fax: [+1] 404-639-8834
bgw2@cdc.gov

MINI-MINUTES - VISI WORKING GROUP CONFERENCE CALL
21 MARCH 2001, 11:00 EST

1. PARTICIPANTS

CBER/FDA
Karen Chaitkin
Maryann Gallagher
Fred Varicchio
CDC
Bruce G. Weniger
Pat Thomas
Chiron Corporation
Jayne Gilbert
Health Canada
Wikke Walop
Merck & Co.
James Mundt
Bruce Rambacher
PFP Consultants
Ronald Filipski
Swedish Institute of Infectious Disease Control
Harald Heijbel
Uniform Code Council
John Roberts
Wyeth-Lederle Vaccines
Lugene Maher
Sarah Fan

2. COLLECTING INDUSTRY VIEWPOINTS

Ron Filipski (formerly director of filling, packaging, warehousing, and distribution at Connaught,

PMC, and now Aventis Pasteur) indicated the desirability for the industry members of the working group to coordinate their viewpoints and responses to VISI proposals, particularly in the light of currently available technologies, and possible alternatives to the VISI proposals.

Bruce Weniger inquired whether this was in order to provide suggestions and feedback on the current draft content of the application guidelines in order to be reflected therein, versus in order to develop an industry reaction to the suggestions once the VISI is formally promulgated.

Ron responded it was primarily the former purpose. Bruce welcomed this effort for specific concrete suggestions, particularly on the technical barriers that remain, and expected timelags required before various VISI components could likely begin appearing in vaccine products. Bruce also said any language proposed about potential alternatives to VISI components might be able to be added to the VISI text. He cited as an example the perhaps-only-somewhat facetious analysis made in the past by industry that it might be less expensive for them to furnish all immunization providers with barcode scanners and computers than to change their filling lines to affix peel-off stickers with online-printed barcodes. (The stickers are principally to serve non-computerized clinics with only paper medical records.)

Wikke Walop, Jayne Gilbert, and James Mundt agreed with Ron's suggestion for what would be an industry subcommittee, and with Ron's offer to coordinate it. It was suggested that this group discuss between now and the next VISI conference call (in 2 months), and that it prepare written feedback and suggestions for changes to VISI content for circulation to the WG and discussion at the next VISI call.

Lugene Maher and Bruce commented on the underlying question about formal FDA reaction to various changes and additions VISI is proposing for vaccine packaging. The worry is that manufacturers will invest time and effort preparing for such changes to their product packaging, but when prototypes are presented to the FDA for formal approval, they will be rebuffed by officials unaware of the VISI process or unsupportive of its guidelines. Lugene said industry had experience with somewhat similar regulatory circumstances in the past.

Bruce pointed out the difficulties inherent in any large agency like CDC or FDA in which the right hand is often not aware of what the left hand is doing. He urged that the part of FDA involved with approving labelling changes on vaccines be kept informed by the VISI working group members from FDA, so that the final VISI guidelines will reflect the FDA stance on these issues. Mary Ann

Gallagher, Karen Chaitkin, and Fred Varicchio pointed out that Bill Purvis is the key vaccine packaging official at CBER. Bruce said Bill is already on the working group and gets all the emails, but because he was not on today's call, he asked that the other FDA participants keep him informed of the discussion and issues.

Finally, on the technology availability subject, John Roberts mentioned that www.pharmex.com is one company he is aware of that supplies peel-off stickers suitable for thermal or laser online printing.

3. RSS« + COMPOSITEÖ versus DATA MATRIXÖ Barcode Symbology

James Mundt said Merck was examining the use of Data Matrix barcoding symbology for internal company use worldwide, and the issue had come up whether or not this symbology would be better for the VISI peel-off stickers than the RSS+Composite standard currently proposed by VISI.

Bruce Weniger indicated the choice of which small-space coding to use was the subject of a VISI conference call some time ago, with representatives of both symbologies involved. He invited John Roberts to explain the pros and cons of each. John pointed out that RSS is the miniaturized 1-dimensional barcode containing the National Drug Code (NDC), while the Composite is the 2-dimensional component that sits above it and can contain the expiration date, lot number, and other information. These symbologies are the creation of a voluntary, not-for-profit, membership organization of retail and wholesale manufacturers and distributors -- the Uniform Code Council (UCC) -- which in 1997 began examining the barcoding needs of space-constrained products, and ultimately selected the RSS + Composite as its standard, over other options, and put them into the public domain.

John pointed out that although Data Matrix symbols could be embedded with the identical number strings to satisy EAN-UCC national and global trade identication standards, Data Matrix is not recognized by the UCC, and thus could not be used in retail commerce.

Bruce pointed out his understanding that Data Matrix can pack more information into a specific unit of area than can RSS + Composite, and can tolerate printing errors better. But one disadvantage is that Data Matrix requires more expensive image scanners to be read. This would be a burden on health clinics, for whom the common laser scanners seen at checkout counters would be several hundred dollars less expensive. "Rastering" laser scanners that can sweep in a vertical dimension are needed to read the 2-dimensional composite barcode, but even the cheapest <$100 wand scanner could still read the 1-dimensional NDC to identify the vaccine.

Bruce pointed out that Data Matrix was in the public

domain, too, as he learned at the website of the current owners of the Data Matrix technology <www.cimatrix.com/acuitycimatrix/index.htm>. He said image scanners capable of reading Data Matrix could also read RSS + Composite, so that the same imager a company might use to track supply components coded with the former symbols could also read and verify the latter ones on finished products. John pointed out that the discrimination between one type of barcode symbol another on the same package would occur in the software receiving the number strings passed along by the imager scanner, and deciding what to do with them.

James Mundt mentioned that Merck's filling lines would need to print the RSS + Composite barcodes on stickers during the filling operation ("online") at speeds of 300 labels per minute. He asked whether that speed was yet attained by printing technology. John responded that he thought performance was quite close to that, and he promised to mail out label-printing samples he had from a recent test run documenting the speeds and resolutions. Jim suggested further meetings on the latest online printing technology. John offered to schedule another session with Rick Fox of Fox IV Technologies <www.foxiv.com>, an expert in this field who has consulted in the past with the VISI.

4. PROGRESS IN FORMATTING VISI DOCUMENTATION

Bruce Weniger updated the working group on the lack of progress at CDC in identifying a computer/webmastering specialist through task order contract to reformat the VISI website and prepare it for the public comment phase and final promulgation phase. But administrative efforts are continuing. On the other hand, the work is underway to prepare the written, printed version to serve in its Adobe portable document format (.pdf) as the official VISI promulgation.

Bruce apologized that a sample posted on the website <www.cdc.gov/nip/visi/prototypes/VISI0316-SampleforWG.pdf> still needed tweaking to avoid a 6-minute wait to paint the VISI logo on page 1. [Hence, the need for the webmaster]. Pat Thomas, the editor, said the hard work to organize a layout for the document was over, and that things would progress more quickly pulling in the content from the existing website and reorganizing and editing it.

5. CANADA PROGRESS ON VACCINE IDENTIFICATION

Although not on the planned agenda, Wikke Walop reported on the Canadian efforts to promulgate standards for vaccine labeling. In a June or July meeting, they will discuss using numerical and alphanumeric strings to identify vaccines in conformance with Canada Institute of Health Information (CIHI) standards. [These will correspond roughly to the use of the NDC and abbreviations in the VISI

proposals.]

Bruce mentioned that Canada has already moved on proposing rules on vaccine packaging, such as plans to mandate three triplicate peel-off stickers for each dose of vaccine (VISI currently specifies one, and leaves open the possibility of duplicate or triplicate stickers). Wikke offered to brief the working group more fully on Canada's progress at the next VISI conference call.

6. SCHEDULING OF NEXT VISI WORKING GROUP CONFERENCE CALL

It was decided to hold the next VISI WG call on Wednesday, 16 May 2001, at 11:00 am EST in order to provide the industry subcommittee time to organize and present its viewpoints in writing to the working group in advance of this call.

7. EUROPE CALLING

Upon the termination of the call at 11:40 EST, Harald Heijbel spoke up, after some WG members had already disconnected. Harald indicated he was in Switzerland at the moment to address a vaccinology conference and that he planned to brief the European attendees on the VISI. He would also try to learn what happened to the aborted European initiative to develop vaccine abbreviations. Their 3-letter, capitalized format was the origin for the "main root" abbreviations of VISI.

Bruce commented to Harald that although abbreviations are the most tangential part of the VISI proposals, they are the most controversial, as they are subject to longstanding personal habits and thus strong opinion. For VISI, they would be used primarily on space-contrained peel-off stickers to substitute for increasingly lengthy generic names to identify the vaccine type in human-readable text (as well as in the Vaccine Facts sidebars). But if FDA were to deem sufficient only providing the shorter tradenames on such stickers, the abbreviations could be spun off from VISI as an independent proposal. Informal, voluntary adoption of an abbreviation nomenclature by vaccine researchers, scientific journal editors, regulatory agencies, and clinicians may require years of consideration over their utility, flexibility, and universality for the many new vaccines being developed and appearing in the years ahead.

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